IN THE SPECIFICATION:

Please replace the paragraph at page 1 at lines 15-20 ([4] of the published application) with the following:

The ground demineralized bone matrix (DBM) has also been called demineralized bone (DMB), and demineralized freeze-dried bone allograft (DFDBA). DFDBA materials are provided for clinical use in a freeze-dried state. DBM (or DMB) can be provided for clinical use in either a freeze-dried state or [[as]]a hydrated state--usually in some form of an aqueous carrier, for example, glycerol in GRAFTON™ (GRAFTON™ is a registered trademark of Osteotech, Inc., Shrewsbury, N.J.), pluronic polymer in DYNAGRAFT™ (DYNAGRAFT™ is a registered trademark of GenSci Regeneration Technologies, Inc., Irvine, Calif.), and collagen in OPTIFORM™ (OPTIFORM™ is a registered trademark of Regeneration Technologies, Inc., Alachua, Fla.). These various commercially available demineralized bone products primarily contain demineralized cortical ground bone distributed for clinical applications. The use of carriers with demineralized bone particles [[are]] is more acceptable to clinicians because such particles acquire a static charge in the dry state making them difficult to dispense into containers and following rehydration, the clinician typically has difficulties in getting the bone particles to remain at the implant site and in a compacted state wherein they are presumed to be most osteoinductive. DBM is considered to be osteoinductive if it induces the formation of new bone, for example, at the site of clinical application. By adding carriers to the DBM, the biomaterials become easier to aliquot into containers and tend to remain tightly aggregated at the implant site making them easier to handle.

Please replace the paragraph at page 3 line 12-page 4 line 5 ([6] of the published application) with the following:

On the other hand, binding at the physical level in the context of surface patterning has been described, for example, in Goodman, et al. (Biomaterials. 1996. 17(21):2087-95). Goodman et al. described clinical and experimental investigations on manufactured surface topographies that have significant effects on cell adhesion and tissue integration stating that micro- and nano-scale mechanical stresses generated by cell-matrix adhesion have significant effects on cellular phenotypic behavior. Details of surface patterning effects on cell attachment and proliferation

were described by Schmidt and Van Recum (Biomaterials. 1992. 13(15):1059-69) measuring macrophage responses to microtextured silicone. Schmidt and Van Recum measured the effects of seven different silicone surface textures on macrophage spreading and metabolic activity in vitro. Variables of the textured arrays important to cell spreading and metabolic activity included size, spacing between, depth, density, and orientation of the individual surface events and the roughness of the surfaces. It was found that pattern dimensions of about 5 micron[[s]] textures were associated with small cells, whereas a smooth (untextured) surface was associated with large cells. The authors put forth a hypothesis that included a possible mechanism of how a micrometer-sized surface texture could modify cell function.

Please replace the paragraph at page 7 line 15-page 8 line 4 ([14] of the published application) with the following:

According to one exemplary embodiment of the present invention, the base is mounted on a slide mechanism, which moves along the predetermined cutting path. An actuation unit, such as a pneumatic actuator, can be used to supply the force necessary for moving the slide mechanism. According to one specific implementation of the present invention, the first actuation unit generates a force ranging between 600 lbs-900 lbs, and preferably about 750 lbs. A second actuation unit can also be provided to control the clamping mechanism. The second actuation unit can be configured to generate a force ranging from 150 lbs-250 lbs, and preferably about 200 lbs. The present invention can also include a computer controller for controlling operation of the substrate cutting device, including the first and second actuation units. For example, the computer controller can be used to adjust the force applied by the first actuation unit and/or adjust the speed at which the slide mechanism is moving. The computer controller can also be used to adjust the force applied on the substrate during the cutting process.

Please replace the paragraph at page 8 at lines 5-10 ([15] of the published application) with the following:

According to another aspect of the present invention, a method for cutting a substrate comprises the steps of: placing the substrate into a substrate cutting device; applying a predetermined force on the substrate; moving a substrate cutter along a grain direction of the

substrate; cutting substrate fibers from the substrate; detecting when the substrate has reached a predetermined minimum thickness; and terminating the process if the substrate has reached the predetermined minimum thickness.

Please replace the paragraph at page 12 at lines 1-6 ([45] of the published application) with the following:

The term, "bone material composition," means a composition comprising the bone fibers or bone fibers plus anorganic or inorganic components mixed with the bone fibers of the present invention and bone-forming cells. Typically, this combination has physical characteristics that allow infusion of ~~visous~~ viscous materials such as bone marrow and osteoinductive effect so as to allow the bone-forming cells to form into new bone cells under appropriate conditions.

Please replace the paragraph at page 12 line 21-page 13 line 2 ([51] of the published application) with the following:

The "substrate" of the present invention may be any material, i.e., non-biological or biological materials, which may be cut using the cutting device of the present invention. Where the substrate is bone, for example, the bone fibers act as a material upon which ~~organism~~ cells such as bone-forming cells may grow or attach.

Please replace the paragraph at page 14 at lines 4-8 ([55] of the published application) with the following:

Production of bone fibers begins with the procurement of bone suitable to the preparation of fiber bone and includes any bone in an animal, such as [[bone]] diaphyseal shafts of long bones, for example the femur, tibia, humerus, ribs, radius, fibula. In humans, such bones are composed primarily of cortical bone tissue, but may also include cancellous bone.

Please replace the paragraph at page 16 line 18-page 17 line 17 ([61] of the published application) with the following:

For demineralization, the mineral content of the bone fibers may be removed using any known process for demineralization causing the bone fibers to be demineralized. Preferably, the

bone fibers are demineralized to contain calcium at a level of from about 0.5 wt % to about 4.5 wt %, more preferably from about 1.0 wt % to about 4.0 wt %, and most preferably from about 1.5 wt % to about 3.5 wt %, for example, as disclosed in U.S. Pat. Nos. 6,189,537 and 6,305,379; and co-pending U.S. Patent application Ser. Nos. 09/655,711 and 10/180,989, the disclosures of which are herein incorporated by reference in their entireties. Once demineralized, the bone fibers may optionally be combined with agents including for example, biological carriers, bioactive agents, or other agents including for example, surface active agents, preservatives including for example glycerol, and inorganic mineral compositions, either before or after further processing, such further processing including but not limited to, freeze-drying, terminal sterilization processes, and/or retaining as a hydrated fiber bone in the presence or absence of preserving agents, or combined immediately prior to implantation in a patient. Moreover, the bone fibers of the present invention may be further combined with other carriers and agents as one having ordinary skill in the art would appreciate for example the use of DMBs. For example, suitable biological carriers include collagen, gelatin, saccharides, fibrin, fibrinogen, alginates, hyaluronins, methylcelluloses, and biologically compatible thixotropic agents. Suitable bioactive agents include but are not limited to, bone morphogenic proteins, stem cells, blood, blood elements, bone marrow and bone marrow extracts, platelets and platelet extracts, homogenates of skin and skin homogenate extracts, growth factors, selenium and ~~transfeffin~~ transferrin, calcium salts, and CYMETRA™.

Please replace the paragraph at page 17 at line 18-page 18 line 9 ([62] of the published application) with the following:

Production of demineralized bone biomaterials and the induction of new bone by these biomaterials are described in U.S. Pat. Nos. 5,275,954, 6,189,537 and 6,305,379, all of which are herein incorporated by reference in their entireties. The bone fibers of the present invention may induce or promote new bone formation by serving as a source of one or more chemoattractants that diffuse from the bone biomaterials to cause cells to migrate to the implanted bone fibers wherein cells adhere to the bone particles (normal mammalian cells are "attachment dependent," meaning they typically require attachment to some surface in order to function metabolically) and differentiate towards a chondrocytic (cartilage forming) or osteocytic (bone forming)

phenotype. In accordance with the present invention, it is believed that surface characteristics of the bone fibers of the present invention render the fibers more accessible and are a more accepting substrate to receive and bind bone-forming cells. Thus, the surface characteristics of the bone fibers may result in improved cell attachments, and consequently, act as a means for selectively attaching cartilage or bone-forming cells from a mixed population of cells, such as are present in platelet-rich plasma, blood, blood products, or bone marrow.

Please replace the paragraph at page 20 line 10-page 21 line 17 ([68] of the published application) with the following:

In one aspect of the invention, the bone fibers of the present invention allow for the formulation of "bone material compositions" comprising the bone fibers for use in bone implants. These bone material compositions provide increased accessibility of the bone fibers to bone-forming cells by permitting suitable voids through which viscous solutions of platelet rich plasma, bone marrow, blood or blood products may flow. For example, the bone fibers may be demineralized and compacted to form a bone material composition suitable for implantation. Because the bone fibers of the present invention are easily handled without breaking apart, the bone fibers may be molded to create an implantable composition, which retains its shape in the implant and further has appropriate spacing through which such solutions comprising bone-forming cells may pass. These bone material compositions may further have integrated therein other components, such as inorganic particles, organic particles, or more specifically non-demineralized cancellous or cortical bone chunks, which may increase the ability of such solutions to flow through the composition by providing structural spacing of the fiber bone. Under such conditions, the surface of the fiber bone fibers would be presented to the infiltrating bone marrow/platelet rich plasma preparations to promote cellular attachment, selectively concentrating the cells most appropriate to the formation of bone or cartilage when the bone material composition is then implanted into some clinical site in the body. Such ex-vivo exposure of the bone fiber biomaterials to osteogenic or chondrogenic cells would serve to concentrate cells that would normally be expected to migrate into the implanted materials through the normal chemoattractive properties of demineralized bone. Thus, this pre-implantation exposure of cells to the bone fibers should reduce the time required for the initiation

of new bone formation and lessen the clinical times needed to ~~affect~~ effect a repair of the damaged site in the body, i.e. a broken bone or fusion site in an intervertebral fusion procedure for repair of cervical or lumbar complications in the spine. Other suitable components for integration into the bone material include, but are not be limited to, inorganics such as particulate calcium salts, such as calcium phosphates, calcium sulfates, and/or calcium carbonates, organics such as particulate ~~skins~~ skin, particulate cartilage, particulate tendons and ligaments, particulate dextrans, particulate alginates, and particulate resorbable and non-resorbable synthetic polymeric materials.

Please replace the paragraph at page 22 at lines 5-14 ([70] of the published application) with the following:

In another aspect of the invention, the bone fibers of the present invention have exhibited superior properties for the formation of bone implants. Bone implants may be formed using the bone fibers of the present invention based on their ability to be easily handled for molding, retaining its shape, and allowing appropriate spacing for biological solutions to pass therethrough even upon compaction. For example, the fibers may be hydrated, which renders [[then]] them pliable and malleable, but capable of retaining its shape without losing durability. In fact, the fibers have been shown to retain its integrity even upon hydration, molding, and subjection to other bone implant-forming treatments. Therefore, the bone fibers of the present invention have superior properties making them ideal for the formation of bone implants.

Please replace the paragraph at page 23 at lines 8-21 ([74] of the published application) with the following:

A first actuation unit 122 generates [[to]] the force necessary to move the slide mechanism 116. According to the disclosed embodiment of the invention, the first actuation unit 122 is pneumatically operated. It should be noted, however, that the first actuation unit 122 can also be operated hydraulically, electrically, and/or mechanically depending on the specific requirements. As illustrated in FIGS. 5 and 6, the first actuation unit 122 includes an air cylinder 124 that receives pressurized air to generate the forces necessary for moving the slide mechanism 116. Referring additionally to FIG. 7, a plurality of pneumatic cables 126 are used to supply air

to the air cylinder 124. Preferably, the air is pressurized at an external location and transferred to the substrate cutting device 100. According to such an arrangement, the pressurized air can optionally be processed in order to maintain sterile environment, when necessary. FIG. 7 also illustrates a foot pedal 128 which can be used to control the operation of the substrate cutting device 100. A computer controller 188 can also be provided to monitor and control operation of the substrate cutting device 100.

Please replace the paragraph at page 26 line 18-page 27 line 8 ([81] of the published application) with the following:

Turning now to FIGS. 11 and 12, additional features of the base 110 will be discussed. The substrate cutting device 100 can include a fiber receptacle 154 for collecting substrate fibers that have been cut. FIG. 16 illustrates a plurality of fibers that have been collected in the fiber receptacle 154. The fiber receptacle 154 is inserted into the base 110 such that it is aligned with the cutter 114 and the fiber channels 148. Accordingly, the cut fibers will fall directly into the fiber receptacle 154. A plurality of guides 156 (best seen in FIG. 12) are provided to properly align the fiber receptacle 154. A locking clip 158 can optionally be used to secure the fiber receptacle 154 in place. It should be noted, however, that various other methods and arrangements can be used to secure the fiber receptacle 154 in place. A receptacle door 160 is used to cover the fiber receptacle 154 and prevent access during operation of the substrate cutting device 100. The receptacle door also includes a reflector (not shown), such as the reflector 196 on the slide mechanism 116, that allows sensor device 190d to determine whether the receptacle door 160 is closed.

Please replace the paragraph at page 29 at lines 9-22 ([87] of the published application) with the following:

FIGS. 17 and 18 illustrate a plurality of wheel type cutters 198 (or wheel cutters) that can be used with an alternative embodiment of the present invention. The wheel cutters 198 are mounted on a base such that they may be rotated and brought into contact with the substrate. The wheel cutters 198 can be designed with various features to produce fibers having desired properties. For example, the thread depth of the wheel cutters 198 can be increased in order to

produce fibers having an increased thickness. Varying the pitch of the wheel cutter 198 will ~~effect~~ affect the length and curvature of the fibers produced. As shown in FIG. 19, a substrate path 200 is used to bring the substrate in contact with the wheel cutter 198. When the pitch of the wheel cutter 198 rotates clockwise relative to the substrate, a "pulling" effect results. This requires less force on the substrate during the cutting process, and produces fibers that are short and curly. When the pitch of the wheel cutter 198 rotates counter-clockwise relative to the substrate, a greater force must be applied in order to maintain contact with the wheel cutter 198. However, the resulting fibers can be longer and will have very consistent dimensions.

Please replace the paragraph at page 30 at lines 10-17 ([89] of the published application) with the following:

Once all access doors are determined to be closed, control passes to step S318. The clamp is then activated. As previously discussed, this can be accomplished by a second actuation unit applying pressure on the substrate. At step S320, the cutter is activated. At step S322, the sensor devices are checked to see if the substrate size has been reduced to a thickness, which is less than a minimum value. If the substrate thickness is greater than the minimum value, then control returns to step S322 and the cuter remains active, i.e., continues to cut the substrate. If the substrate thickness is less than or equal to the minimum value, then the system is stopped as step S326.

Please replace the paragraph at page 31 at lines 3-20 ([91] of the published application) with the following:

Diaphyseal shafts (total of ~~approximate~~ approximately 520 grams wet weight of bone material) from the long bones and ribs of a given donor (human donor information is confidential) were mechanically debrided (as disclosed in co-pending U.S. patent application Ser. No. 10/108,104, incorporated by reference herein) to remove associated periosteal tissue and bone marrow in the intramedulary canal. The shafts and ribs were then cut into linear pieces with widths, thickness, and lengths approximating <45 mm x <45 mm x 6 cm using a bone saw. A cut piece of cortical bone (wet weight 48 grams) was then loaded individually into the load chute of the cutting device and the clamping cylinder was locked into the closed position. The cutting

slide having the cutting blade disposed therein was activated and cut fiber bone was collected into the receiving bin. A total of 42 grams of fiber bone were accumulated during the 60 cutting cycles (cutting cycle equals one back/forth pass of the cutter/cutter slide across the bone surface) for approximately 70 seconds with additional bone materials being added to the feeder chute at each cutting event. After each cutting event, another cortical shaft and/or cortical pieces were added and another cutting event was initiated. The amount of the bone materials loaded into the chute for each cutting event varied. However, the number of cutting events performed were sufficient to accumulate a bulk fiber mass of approximately 490 grams (wet weight).

Please replace the paragraph at page 32 at lines 8-21 ([93] of the published application) with the following:

Aliquots of the demineralized fiber bone were removed from a sterile container and transferred to the animal implantation laboratory. Aliquots of fiber bone (20 and 40 mg wet weight) were manually compacted and implanted intramuscularly into the hindquarters of athymic (nude) mice as compressed fiber bone materials using established Institutional Animal Care and Use Committee approved protocols (Old Dominion University). After 28 days of implantation, the implanted materials were explanted and the explants fixed in formaldehyde. The fixed explants were embedded in ~~parafin~~ paraffin and sectioned for use in preparation of histology slides. The prepared histology slides were stained using Hematoxylin and Eosin (H&E staining) and viewed under the microscope for induced new bone formation. The induced new bone formation is illustrated in FIG. 3. Induced new bone formation was determined using histomorphometry and the bone materials were determined to have induced significantly more new bone than non-osteoinductive controls, i.e. the fiber bone was deemed to be osteoinductive using the nude mouse bioassay model.